UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,153	03/17/2004	Michael V. Chobotov	1880-10 CONII/RCE	5039

23869 7590 08/28/2008
HOFFMANN & BARON, LLP
6900 JERICHO TURNPIKE
SYOSSET, NY 11791

EXAMINER	
MILLER, CHERYL L	

ART UNIT	PAPER NUMBER
3738	

MAIL DATE	DELIVERY MODE
08/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/803,153	CHOBOTOV, MICHAEL V.	
	Examiner	Art Unit	
	CHERYL MILLER	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1 and 4-18 have been considered but are moot in view of the new ground(s) of rejection.

Because the examiner has maintained both the Fogarty (US 6,123,722) and Marcade (US 5,683,449) rejections, the examiner has responded to applicants corresponding arguments.

The applicant has argued that Fogarty does not disclose graft members that completely overlap the lesion. The examiner disagrees for several reasons. First, the product claims only require the capability of graft members to overlap a lesion, Fogarty's graft members have this capability (a specific sized lesion is not claimed, the lesion could be small or large, and the length of Fogarty's members each has a sufficient length that would be capable of overlapping a lesion). Second, the claims require the graft members (as a combination) to completely overlap a lesion. Fogarty's graft members (for example 66+64+62 combined) completely overlap the lesion as shown in fig.5c. Each individual graft member is not required by the claim to have a length longer than the lesion. Further, although Fogarty has only shown the graft members to partially overlap one another, the graft members clearly have the capability to fully overlap one another, as the function of a overlap is already shown in the figures and Fogarty further discloses tailoring the amount of overlap to the patients needs (col.3, lines 14-37; col.4, lines 13-18; col.6, lines 63-67).

The applicant has argued that Marcade does not disclose any graft components that singularly completely overlap a lesion. However, this is not what applicant has claimed. The applicant has not claimed each component to have a length longer than the lesion. The applicant

has claimed that the graft components (as a whole or combination) completely overlap the lesion. Marcade's graft elements (100, 112, 114, and 116) together span the total length of the lesion, see fig.3J. It is further noted that applicant has not claimed a specific size lesion. Therefore the individual graft components each have a length sufficient to completely overlap a small sized lesion (the lesion shown in fig.3J is one of the largest lesions in the body, thus clearly has the capability of spanning smaller lesions). Further, Marcade's graft components have sizes similar to applicant's graft components thus inherently are capable of spanning any lesions that applicant's components span.

It is noted that a complete overlap of a lesion is not given weight in a product claim. The product claims *only need to posses the capability* of overlapping a lesion. Relative positioning in the body is a method step, is not part of the structure of the product and is not given patentable weight in a product claim. Positioning of the product in the body at the lesion is given weight in the method claims as it is a step of implantation.

Claim Rejections - 35 USC § 101

Claims 1 and 4-8 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 1 recites, "graft members completely overlap the preselected length of the patients body lumen" in line 6 and "graft members completely overlap the lesion" in line 14. Each positively recites a portion of the body which is considered non-statutory subject matter. Each positively recites the grafts position with respect to the body lumen. This format is incorrect. It is suggested to change the above to recite, --graft members are configured (or adapted) to completely overlap the preselected length of the patients body

lumen--. Claim 4 contains similar problems. Claims 5-8 depend upon claim 1 and inherit all problems associated with the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4-5, 7-8, 11-15, 17, and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Fogarty et al. (US 6,123,722, cited previously). Fogarty discloses an endovascular graft or kit (60, 90) comprising a plurality of separate thin walled graft members (62, 64, 66; 92, 94) configured to be layered (Fogarty's graft are *capable of* being layered; see figs.3-5). Fogarty discloses two or three graft members, together being able to support a body lumen (col.3, lines 56-65) and completely overlap a lesion in the lumen (see fig.5c). Fogarty discloses one of the graft members (64 for example in fig.3 or 94 in fig.4, *configured to be placed* on the inner most location) having the greatest length. Fogarty discloses the graft members to be capable of being delivered individually (fig.5; col.6, lines 55-68). Fogarty discloses anchoring mechanisms (barbs 83 or flare seen in fig.6c) on the ends of the graft members. Fogarty's "desired amount" of support in the overlapping graft areas is the amount of support provided by two graft members, and inherently the one graft would not provide the "desired amount", since in the area of overlap, there are two grafts and thus the "desired amount" of Fogarty in the overlapping area is the

amount of support provided by two grafts, not one. Also, each member is a stent-graft, and the graft members alone do not provide the support to the vessel, it is the stent that provides the support to the graft and to the vessel (col.6, lines 2-6; col.9, lines 7-8), and therefore, all grafts used alone would not provide sufficient strength to hold open the vessel. Fogarty discloses delivering a first graft (62) and a second graft (64), the grafts (62+64) completely overlapping the lesion (see fig.5c; components 64+62 combined span the length of the lesion).

Claims 1, 4, 5, 7, 8, 11-15, 17, and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Marcade (US 5,683,449). Marcade discloses a endovascular graft kit (fig.2) comprising a plurality of separate thin wall graft members (152 of 110, 112, 114, and 116) configured to be layered, the graft members *configured* to have a length longer than a length of the patients lumen, wherein no single graft member has sufficient mechanical strength to provide a desired amount of support to the lumen (graft members 152 of each component is made of the same materials as disclosed by the applicant-Dacron or ePTFE and of the thickness disclosed by the applicant, 0.1mm, which is between 0.002 and 0.008 inches, col.12, lines 5-20; thus inherently Marcade's graft members will have the same strength characteristics as the applicants graft members), the graft members configured to provide the sufficient strength over portions that are overlapped (col.18, lines 24-27). Marcade's graft members (110, 112, 114, 116) completely overlap the lesion (shown in fig.3J to completely span the lesion). Marcade discloses anchoring mechanisms (stents 154 OR barbs 156) at the ends of the graft members. Marcade discloses the graft members to be individually delivered (abstract) by a low profile catheter system (300; fig.9-10). Marcade discloses a method comprising deploying a first graft (112) and

a second graft (110) inside the first (fig.3I), the graft components completely overlapping the lesion (see fig.3J; the components together have a length longer than the lesion).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6, 9-10, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fogarty et al. (US 6,123,722, cited previously). Referring to claims 6 and 16, Fogarty discloses a layered endovascular graft (60, 90; fig.3-5; see above) having expansion capabilities on a catheter substantially as claimed (col.9, lines 24-29). Fogarty does not disclose however, the exact dimensions of the catheter diameter nor the compressed graft diameters. It would have been obvious for one having ordinary skill in the art at the time the invention was made to have the claimed dimensions since wherein the general conditions of a claim are disclosed in the prior art (graft members and a catheter having a shown diameter) it is not inventive to discover the optimum or workable ranges (3-40mm and 4mm). *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Referring to claims 9-10, Fogarty discloses a method of deploying a graft comprising providing at least two thin graft members (62 and 64 for example; or any graft components shown in fig.4), delivering one (62 for example) through a catheter (30) and deploying the one, then delivering a second thin graft (64 for example) through a catheter (30) and deploying the second within a lumen of the first (fig.5a-5c; col.6 line 55-col.7 line 5). Although Fogarty does

not specifically shown in the example of fig.5c, each graft member (64 and 62) to completely overlap the lesion (102), Fogarty does disclose using a variety of different length components (fig.4; col.9, lines 24-29; col.11, lines 32-36) and controlling the overlap range of two graft members to tailor to the needs of the patient (col.3, lines 14-37; col.4, lines 13-18; col.6, lines 63-67). Because Fogarty discloses variation of the overlap range and variation of the total length of the grafts, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have graft components that each completely overlap a lesion, since such would make common sense to best support the vessel and provide predicable results of increased support and reduced leakage.

Claims 6 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marcade (US 5,683,449). Referring to claims 6 and 16, Marcade discloses a plurality of expandable graft components configured for delivery separately by a catheter. Marcade discloses or shows the graft members (col.9, lines 22-28; col.10, lines 3-5) and catheter (fig.9, 10) to have a diameter, however does not disclose the exact diameters claimed. It would have been obvious to have the claimed dimensions since wherein the general conditions of a claim are disclosed in the prior art (thin graft members and a catheter having a shown diameter) it is not inventive to discover the optimum or workable ranges (3-40mm and 4mm). *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERYL MILLER whose telephone number is (571)272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cheryl Miller/
Examiner, Art Unit 3738

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738